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HETL

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January 25, 2012

Dear HETL Client:

HETL is pleased to announce the launch of a new HIV screening test, the BIO-RAD[®] GS HIV Combo Ag/Ab EIA. This test is called a 4th generation HIV screening test and will replace HETL's current HIV test, a 3rd generation test. Fourth generation tests, with their ability to detect viral antigen, have been shown to detect HIV infection up to 20 days before a western blot versus 13 days for the third generation test, effectively decreasing the time from infection to detection by approximately 7 days. This is an FDA approved test that detects not only patient antibodies to HIV but also viral antigen.

The HETL will continue to use the Western Blot HIV-1 Test for confirmation. However, the HETL is in the process of comparing the western blot test to the Bio-Rad Multispot assay. The Bio-Rad[®] Multispot assay is an FDA approved HIV-1 and HIV-2 discriminatory test. Replacing the Western Blot Test with the Bio-Rad[®] Multispot is consistent with the recommended guidance from CDC and CLSI document M53-A. Adoption of this test for confirmation will dramatically reduce turnaround time for confirmation of positive HIV screening results. In the event that confirmation tests are negative for a positive 4th generation test, HETL will contact clinical submitters with information on nucleic acid amplification testing.

Effective Monday January 30, 2012 HETL client orders for the HIV-1/HIV-2 serum screening will be processed using the 4th generation HIV screening test. This new test is priced at \$22.00. More specific information for clients can be found at our web site (www.mainepublichealth.gov/lab). Find the link on our home page entitled: "Microbiology Testing: How to Submit Samples" and download the document entitled "HIV-Serum".

Please feel free to contact HETL serology with specific question about the 4th generation HIV screening test at 207-287-1722.

Sincerely,

Kenneth G. Pote, Ph.D.
Chief of Laboratory Operations
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